

PART III: CONSUMER INFORMATION

Pr Atacand[®]
(candesartan cilexetil tablets)

This leaflet is part III of a three-part "Product Monograph" published when ATACAND[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ATACAND[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ATACAND is used to treat hypertension (high blood pressure).

You may not experience any signs of high blood pressure. It is important to take ATACAND as directed by your doctor. If high blood pressure is not treated, damage may result to vital organs such as the heart or the kidneys. High blood pressure can lead to strokes, heart attacks, heart failure, kidney failure, or blindness.

ATACAND can also be taken for treatment of a heart condition known as heart failure. This is a condition in which your heart does not pump blood around your body as well as it should.

It is important to take ATACAND as directed by your doctor.

What it does:

ATACAND is the brand name for this drug, candesartan cilexetil. It belongs to the group of drugs called "angiotensin II receptor blockers". Its main action is to relax the arteries, letting the blood flow more freely, thereby lowering the blood pressure.

When it should not be used:

You should not take ATACAND if:

- You are allergic to "non-medicinal" substances like food products, preservatives, or dyes, which may be present in ATACAND tablets (See What the important nonmedicinal ingredients are).
- You have ever had a bad, unusual or allergic reaction to candesartan cilexetil.

What the medicinal ingredient is:

Candesartan cilexetil.

What the nonmedicinal ingredients are:

Most medicines contain more ingredients than just the active drug. These ingredients are needed to keep medicines in a form that you can swallow. Check with your doctor if you think you might be allergic to any of the following items (listed in alphabetical order): Calcium carboxymethylcellulose, maize starch, hydroxypropyl cellulose, iron oxide (except 4 mg tablets), lactose, magnesium stearate, and polyethylene glycol.

What dosage forms it comes in:

ATACAND is available as 4 mg, 8 mg, 16 mg and 32 mg tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ATACAND should not be used during pregnancy. If you discover that you are pregnant while taking ATACAND, stop the medication and please contact your physician.

Before you start ATACAND be sure you have told your doctor:

- **If you are pregnant, breast feeding or thinking about becoming pregnant.**
Taking ATACAND during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking ATACAND, contact your doctor immediately.
It is possible that ATACAND passes into breast milk. You should discuss with your doctor about taking ATACAND while breast feeding.
- About all health problems you have or have had in the past including any heart, liver or kidney problems.
- If you are taking a diuretic therapy (water pills) or are on salt restrictive diet.
- If you are undergoing dialysis.
- If you are vomiting or have diarrhea.

The treatment of high blood pressure may cause dizziness or weariness in some patients. Make sure you are not affected in this way before driving or operating machinery.

If you are currently taking ATACAND and are going to have an operation, be sure to tell your doctor or dentist about your medication before you are given an anaesthetic.

INTERACTIONS WITH THIS MEDICATION

Before taking ATACAND be sure your doctor knows about all medicines you take, including ones you can buy without a prescription. If you visit more than one doctor make sure that each knows about all the medicines you are taking.

Drugs that may interact with ATACAND include:

- Other medicines used to lower blood pressure, including diuretics (water pills);

- Potassium-sparing diuretics, potassium supplements or potassium-containing salt substitutes;
- Lithium therapy.

PROPER USE OF THIS MEDICATION

Remember, you may not notice any signs of high blood pressure. **Therefore, it is important to take ATACAND even when you feel well.** A constant amount of drug is needed in your body to control your blood pressure. **Do not stop taking ATACAND on your own.**

Usual Dose:

Take ATACAND exactly as your doctor tells you. Do not miss doses or take extra doses, unless your doctor tells you. If you are not clear about the directions, ask your doctor or pharmacist.

The dosage of ATACAND is individualized.

ATACAND is not for use in children under 18 years of age.

Try to take ATACAND with something you do regularly each day; for example, upon waking or at breakfast. This will help you remember each dose.

ATACAND may be taken with food or on an empty stomach but it should be taken consistently the same way each day.

Swallow ATACAND with a glass of water.

ATACAND is taken once a day. Even if your doctor has prescribed 2 tablets a day, both should be taken at the same time, unless otherwise indicated.

To help you keep track of your doses, ATACAND comes in a blister pack with days of the week printed on the back of the blister. Start with the tablet that matches the day of the week and continue taking them in order until they are all finished.

There are 14 days of labeled tablets in each blister, with one extra to make 15. All 15 tablets, including the one labeled "Take this tablet last", are exactly the same. Once you have finished the 14 labeled tablets, take the one marked "Take this tablet last" before starting your next blister pack.

Remember to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

The package protects each tablet. When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.

Do not transfer ATACAND to other pill containers. To protect your ATACAND tablets, keep them in the original package.

Overdose:

If you take more ATACAND than you should, contact a doctor, the Regional Poison Control centre or pharmacist immediately.

Missed Dose:

If you miss a dose of ATACAND and remember within 12 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. But if it is more than 12 hours when you remember, do not take the missed dose. Just take the next dose on time.

Never take a double dose of ATACAND to make up for missed tablets. If you are still unsure, check with your doctor or pharmacist to see what you should do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its effects on controlling blood pressure, ATACAND, like any medication, may cause side effects. These side effects are usually mild and should go away as your body gets used to ATACAND. Talk to your doctor if you suffer from any of these effects or if you get any other unusual or unexpected symptoms.

Common side effects that may occur (in 1% or more of patients but less than 10%):

- Dizziness
- Headache
- Cold symptoms
- Worsening of the kidney function (especially in patients with existing kidney problems or heart failure)
- Abnormally low blood pressure (especially in patients with heart failure)
- High levels of potassium in the blood (especially in patients with heart failure)
- Back pain

Rare side effects that may occur (in between 0.01% and 1% of patients):

- Fainting spells

Very rare side effects that may occur (in less than 0.01% of patients):

- Changes to the way the liver works, including inflammation of the liver

Side effects such as muscle pain, muscle weakness, muscle inflammation and rhabdomyolysis (a muscle-wasting disease), in rare cases leading to kidney failure, have been reported with the use of angiotensin II receptor blockers, the class of drugs to which ATACAND belongs.

Blood samples may be taken occasionally to check whether ATACAND has had any effect on your blood or on your kidneys.

Medicines affect different people in different ways. Just because side effects have occurred in other patients does not mean you will get them. Discuss how you feel on ATACAND with your doctor and pharmacist. **Do not stop taking ATACAND on your own.**

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist*
		Only if severe	In all cases	
Rare	Allergic reactions: swelling of the face, lips, tongue and/or throat; rash or other skin reactions			X
	Jaundice (yellow skin and/or eyes)			X
	Muscle pain that you cannot explain, muscle tenderness or weakness, generalized weakness		X	
	Dark/brown urine		X	

**If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.*

This is not a complete list of side effects. For any unexpected effects while taking ATACAND, contact your doctor or pharmacist.

HOW TO STORE IT

- Although the ATACAND tablets are protected in their package, it is best to keep the package at normal room temperature and in a dry place. Do not keep ATACAND in the bathroom.
- **Keep ATACAND out of sight and out of reach of children.** Never take medicine in front of small children as they will want to copy you.
- Do not keep or use ATACAND after the expiry date indicated on the package. Unused medicines which you know you will no longer need should be carefully discarded. You may wish to seek advice from your pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program, collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

All drugs can have both helpful and harmful effects. Both depend on the person and his or her health condition. This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about ATACAND.

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc. at: Customer Inquiries – 1 (800) 668-6000, Renseignements – 1 (800) 461-3787.

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